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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS)
CORPORATION,)
Plaintiff,) **DOCUMENT**
v.) **ELECTRONICALLY FILED**
ACTAVIS LLC; APOTEX, INC.;)
APOTEX, CORP.; GLAND PHARMA)
LTD.; DR. REDDY'S LABORATORIES,)
INC.; DR. REDDY'S LABORATORIES)
LTD.; EMCURE PHARMACEUTICALS)
USA, INC.; EMCURE)
PHARMACEUTICALS, LTD; HOSPIRA,) Civil Action No. 13-cv-1028-SDW-MCA

INC.; PHARMACEUTICS)
INTERNATIONAL INC.; SAGENT)
PHARMACEUTICALS, INC.; ACS)
DOBFAR INFO S.A.; STRIDES, INC.;)
AGILA SPECIALTIES PRIVATE LTD.;)
SUN PHARMA GLOBAL FZE;)
CARACO PHARMACEUTICAL)
LABORATORIES, LTD; SUN)
PHARMACEUTICAL INDUSTRIES)
LTD.; WOCKHARDT USA LLC; and)
WOCKHARDT LTD.)
Defendants.)

**WOCKHARDT USA LLC AND WOCKHARDT LTD.'S MEMORANDUM IN SUPPORT
OF THEIR MOTION TO DISMISS COUNT II OF THE CORRECTED AMENDED
COMPLAINT**

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Defendants Wockhardt USA LLC and Wockhardt Ltd. (collectively, “Wockhardt”) move the Court pursuant to Fed. R. Civ. P. 12(b)(6), for an Order dismissing Count II of the Corrected Amended Complaint¹ filed by Plaintiff Novartis Pharmaceuticals Corporation (“Novartis”).

I. INTRODUCTION

Civil Action No. 13-cv-1028-SDW-MCA (“the 2013 Litigation”) is, in part, duplicative of a patent infringement case regarding U.S. Patent 8,052,987 (“the ’987 patent”) already in progress between Novartis and Wockhardt. In deciding whether Novartis’ Count II of the 2013 Litigation Corrected Amended Complaint states a claim upon which relief can be granted this Court need look no further than Novartis’ own admissions. Novartis specifically explained to Magistrate Judge Arleo in Civil Action No. 12-cv-3967-SDW-MCA (“the 2012 Litigation”) that:

While the new lawsuit asserts the ’987 patent against several generic defendants, because Novartis had already sued Wockhardt for infringement of the ’987 patent in this case, the new suit added allegations that Wockhardt was infringing the ’189 patent, ***but did not repeat the allegations of infringement of the ’987 patent.***

(2012 Litigation, D.I. 51, p. 2 (emphasis added).) Moreover, even if Novartis had not already admitted that the allegations of infringement of the ’987 patent were not asserted against Wockhardt, Count II of the 2013 Litigation Corrected Amended Complaint is nothing more than an improper attempt to use this second litigation as a vehicle to undo and revisit Novartis’ earlier, binding decisions in the 2012 Litigation—specifically, its decisions to bring suit against Wockhardt with respect to the ’987 patent, and then not to assert any claims of the ’987 patent in the disclosure required by the Local Patent Rules of this Court.

¹ Novartis’ Corrected Amended Complaint was filed improperly under Federal Rule of Civil Procedure 15(a). A party may amend its pleading only once as a matter of course. See Fed. R. Civ. P. 15(a). Novartis did not seek leave of the Court to file its Corrected Amended Complaint. However as the allegations to Wockhardt are the same in both the Amended Complaint and the Corrected Amended Complaint, Wockhardt addresses the Corrected Amended Complaint in this Motion.

The 2012 Litigation began on June 27, 2012, when Plaintiffs Novartis, Novartis Corp., and Novartis AG first filed suit against Wockhardt alleging that Wockhardt's proposed generic versions of ZOMETA® and RECLAST® would infringe U.S. Patent 7,932,241 ("the '241 patent") and the '987 patent. (*See* 2012 Litigation, D.I. 1, Complaint.) On October 12, 2012, pursuant to Local Patent Rule 3.6(b), Novartis was required to identify the specific patent claims it was asserting against Wockhardt. Novartis chose only to assert claims from the '241 patent. (*See* Confoy Decl. Ex. 1, Disclosure of Asserted Claims.) Thus, Novartis dropped its claims with respect to the '987 patent. In reliance on Novartis' identification of Asserted Claims, which did not include the '987 patent, the parties in the 2012 Litigation subsequently exchanged invalidity contentions, infringement contentions, discovery requests and responses, deposition notices, claim terms to be construed, and proposed claim constructions. Because Novartis chose not to assert any claims from the '987 patent, it is now precluded from raising any infringement arguments in the 2012 Litigation relating to the '987 patent without first showing good cause and obtaining an order of the Court permitting Novartis to amend its Asserted Claims. *See* N.J. L. Pat. R. 3.6(g) and 3.7. Wockhardt, however, has shown that Novartis does not have good cause for such amendment. (*See* 2012 Litigation, D.I. 53.) Moreover, this Court has already recognized that the alleged change in business strategy, Novartis' sole assertion of good cause, is unbelievable. In the March 1, 2013 Temporary Restraining Order ("TRO") hearing in the 2013 Litigation, this Court rejected Novartis story of "good cause" explaining that:

[I]t strains credibility in my opinion, quite frankly, to say that it that it was only at the time that this '189 patent came around that we realized we can do anything [on the '987 patent]. That just doesn't make sense to me. And I don't think it's supported by the record. I don't think the dates support that. I think that's very clear.

(2013 Litigation, D.I. 131, Mar. 1, 2013 TRO Hearing Tr. 76:23-77:3 (emphasis added).)

Accordingly, Novartis will remain unable to assert the claims of the '987 patent against Wockhardt in the 2012 Litigation.

In light of its inability to show good cause and amend the Asserted Claims, Novartis has sought, and continues to seek, to circumvent this Court's Local Patent Rules by resuscitating the '987 patent in a second suit based on the same core facts as those already involved in the 2012 Litigation. On February 20, 2013, Novartis filed a complaint in the 2013 Litigation. In response to Novartis' reassertion of the '987 patent, Wockhardt moved to dismiss Count II of the original complaint. (2013 Litigation, D.I. 32.) Following Wockhardt's motion to dismiss, Novartis misinformed Magistrate Judge Arleo in the 2012 Litigation that it "***did not repeat the allegations of infringement of the '987 patent.***" (2012 Litigation, D.I. 51, p. 2.) On March 13, 2013, Novartis filed a letter informing the Court, and Wockhardt, that it would be filing an amended complaint and noted that its amended complaint would render moot the pending motions to dismiss. (2013 Litigation, D.I. 116.) In an amazing display of gamesmanship, and to Wockhardt's surprise, Novartis has elected to continue unnecessarily dragging out this duplicative and vexatious action by including Wockhardt in its allegations in Count II of the 2013 Litigation Corrected Amended Complaint, which continues to reassert the '987 patent against Wockhardt.

This Court has already described Novartis' actions as "lead[ing] to the supposition, potentially, that this was about ***gamesmanship.***" (2013 Litigation, D.I. 131, Mar. 1, 2013 TRO Hearing Tr. at 76:11-12 (emphasis added).) Notwithstanding this statement by the Court, Novartis waited until the last minute to amend its 2013 Litigation Complaint, filing it on the last business day before Novartis' opposition to Wockhardt's original motion to dismiss was due and

amending it a second time on March 21, 2013. Novartis' 2013 Litigation Corrected Amended Complaint, asserts for a *third time* that Wockhardt's proposed generic version of RECLAST® would infringe the '987 patent. (*See* 2013 Litigation, D.I. 134, Corrected Amended Complaint.) The 2013 Litigation Corrected Amended Complaint, made no substantive changes to Count II of the 2013 Litigation Complaint. (*Compare* 2013 Litigation, D.I. 134, Corrected Amended Complaint at ¶¶ 81-85 *with* 2013 Litigation, D.I. 1, Complaint, at ¶¶ 88-92.) Accordingly, by delaying until the last minute, Novartis' has successfully obtained additional time to respond to Wockhardt's arguments regarding dismissal. Such additional time is unwarranted where, as here, Novartis made no changes to its original complaint addressing the deficiencies raised by Wockhardt in its original motion to dismiss.

Count II of the 2013 Litigation Corrected Amended Complaint represents nothing more than Novartis' *third* bite at the apple, serving no purpose whatsoever but to circumvent this Court's Local Patent Rules, waste judicial resources, and unfairly prejudice Wockhardt. Accordingly, Wockhardt respectfully requests that this Court dismiss Count II of Novartis' 2013 Litigation Corrected Amended Complaint.

II. LEGAL STANDARD

A court shall grant a party's Rule 12(b)(6) motion when, accepting all of the non-moving party's well-pleaded factual allegations as true the non-moving party is not entitled to relief as a matter of law. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997). To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain sufficient factual matter, if accepted as true to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Comp. v. Twombly*, 550 U.S. 544, 570 (2007)). Affirmative defenses, such as *res judicata* and the entire controversy doctrine, may be proper

grounds for dismissal pursuant to Rule 12(b)(6) when the basis for a dismissal is apparent on the face of the complaint. *See Kisby Lees Mech. LLC v. Pinnacle Insulation, Inc.*, No. 11-5093 (JBS/AMD), 2012 WL 3133681 at *4 (D.N.J. July 31, 2012). As a general rule, a district court considering a 12(b)(6) motion to dismiss relies on “the complaint, attached exhibits, and matters of public record.” *Sands v. McCormick*, 502 F.3d 263, 268 (3d Cir. 2007).

III. ARGUMENT

Count II of the 2013 Litigation Corrected Amended Complaint should be dismissed with prejudice because it is duplicative of Count II already pending in the 2012 Litigation. Litigants are generally precluded from asserting duplicative litigation in federal courts. *See Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976) (“As between federal district courts . . . though no precise rule has evolved, the general principle is to avoid duplicative litigation.”). The power to dismiss duplicative lawsuits not only fosters judicial economy, but protects parties, like Wockhardt, from the vexation of concurrent litigation over the same subject matter. *See Unitronics, Inc. v. Robotic Parking Sys. Inc.*, No. 09-3493, 2010 WL 2545169 at *3 (D.N.J. June 18, 2012) (citing *Curtis v. Citibank, N.A.*, 226 F.3d 133, 138 (2d Cir. 2000)).²

The reassertion of the ’987 patent is also barred by the claim splitting doctrine. *See Walton v. Eaton Corp.*, 563 F.2d 66 (3d Cir. 1977) (Plaintiff who filed a second lawsuit, with claims identical to those in alleged the first lawsuit and claims that could, and should have been, brought in the first lawsuit, was not allowed not maintain two separate suits.) Although the claim-splitting doctrine is an aspect of *res judicata*, the former does not require a final judgment to take effect. *See Katz v. Gerardi*, 655 F.3d 1212, 1219 (10th Cir. 2011) (“If the party

² The Third Circuit has cited *Curtis* approvingly in at least two, non-precedential opinions, dismissing duplicative cases. *See Schneider v. United States*, 301 Fed. Appx. 187, 189 (3d Cir. 2008); *see also Hutchins v. UPS*, 197 Fed. Appx. 152, 159 (3d Cir. 2006).

challenging a second suit on the basis of claim splitting had to wait until the first suit was final, the rule would be meaningless. The second, duplicative suit would forge ahead until the first suit became final, all the while wasting judicial resources.”); Wright & Miller, 18A Federal Practice & Procedure Jurisdiction § 4406 (2d ed. 2011). Moreover, the fact that the 2012 Litigation is encumbered by the contest over Novartis’ ability to amend its asserted claims, does not give Novartis the right to avoid the contest altogether by reasserting the ’987 patent in a new suit. *See Remington Rand Corp.—Delaware v. Business Sys. Inc.*, 830 F.2d 1274, 1276 (where a plenary action was encumbered by a contest over personal jurisdiction, it was improper to file a summary application in a new case, in the same district court).

Count II of the 2013 Litigation Corrected Amended Complaint should be dismissed because it creates a second action on the same subject matter, against the same defendant, at the same time as the 2012 Litigation, in an attempt to avoid this Court’s Local Patent Rules. *See Walton*, 563 F.2d at 71 (“The adoption of an incorrect procedure . . . should not result in a greater right . . . than would have been available had the correct course of amending . . . been followed.”); *Curtis v. Citibank, N.A.*, 226 F.3d 133, 139 (2d Cir. 2000) (“[P]laintiffs have no right to maintain two actions on the same subject in the same court, against the same defendant at the same time.”).

A. Count II of the 2013 Litigation Corrected Amended Complaint Should Be Dismissed Under Rule 12(b)(6) Because it Reasserts the Same Subject Matter as was Already Asserted in the Complaint in the 2012 Litigation

Novartis has already admitted that it “had already sued Wockhardt for infringement of the ’987 patent in [the 2012 litigation]” and alleges that it “did not repeat the allegations of infringement of the ’987 patent [in the 2013 litigation].” (2012 Litigation, D.I. 51, p.2.) According to Novartis’ own admission, the ’987 patent should not be part of the 2013 Litigation.

Contrary to Novartis' representations, however, Novartis has actually asserted in Count II of the 2013 Litigation Corrected Amended Complaint the same allegations that it already asserted against Wockhardt in the 2012 Litigation.

In the 2012 Litigation, Novartis alleged that the '987 patent was infringed by Wockhardt's filing of ANDA No. 203070. (*See* 2012 Litigation, D.I. 1, Complaint, at ¶ 45.) Novartis further alleged that Wockhardt would infringe the '987 patent by "making, using, offering to sell, and selling" its generic RECLAST® product and would "actively induc[e] and contribute[e] to infringement by others in violation of U.S.C. § 271(a)-(c)." (*Id.*, at ¶ 46.) Similarly, Count II of the 2013 Litigation Corrected Amended Complaint alleges that Wockhardt infringed the '987 patent by submitting an ANDA to the FDA for generic RECLAST®. (*See* 2013 Litigation, D.I. 134, Corrected Amended Complaint, at ¶ 82.) Novartis also alleges that Wockhardt will infringe the '987 patent by "making, using offering to sell and selling its [generic RECLAST® product]." (*Id.*) Moreover, Count II of the 2013 Litigation Corrected Amended Complaint mirrors the 2012 Litigation Complaint by alleging that Wockhardt will "intentionally induce [infringement]" and "contribute to infringement of the '987 patent." (*Id.*, at ¶¶ 83-84.)

Novartis has also admitted that the subject matter is the same. Counsel for Novartis certified that "the matter in controversy is the subject of *Novartis Pharmaceuticals Corp. et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA filed on June 27, 2012 in the District of New Jersey." (Certification Pursuant to L. Civ. R. 11.2, 2013 Litigation, D.I. 134, Corrected Amended Complaint, at p. 22.)

Novartis seeks equivalent remedies in both actions, against the same defendants, at the same time. In the 2012 Litigation Complaint, Novartis seeks injunctive relief and damages if Wockhardt engages in "commercial manufacture, use, offers to sell, sale or importation" of a

generic RECLAST® product. (2012 Litigation, D.I. 1, Complaint, at Prayer for Relief 5 and 7.) Similarly, the 2013 Litigation Corrected Amended Complaint seeks “an order permanently enjoining” Wockhardt from “making using, offering to sell or selling in the United States or importing” a generic RECLAST® product and damages if Wockhardt engages in such actions. (2013 Litigation, D.I. 134, Corrected Amended Complaint, at Prayer for Relief 3-4.) The few requests for relief not previously stated in the 2012 Litigation Complaint are founded upon the same issue: whether Wockhardt’s proposed generic RECLAST® product infringes the claims of the ’987 patent.

Novartis is a plaintiff in both the 2012 Litigation and the 2013 Litigation, and Wockhardt USA LLC and Wockhardt Ltd. are defendants in both actions. Because Novartis is using the 2013 Litigation to allege the same claims, arising out of the same subject matter, seeking the same relief, from the same parties, while the 2012 Litigation is still pending, Count II of the 2013 Litigation Corrected Amended Complaint should be dismissed. *See Remington*, 80 F.2d at 1276 (where claims originated in the same federal district, before the same federal judge, displaying the same identity of parties and issues, it would be wasteful and inconvenient for them to be litigated simultaneously.)

B. Denial of Novartis’ Motion to Amend the Asserted Claims in the 2012 Litigation will have No Effect on the Duplicative Nature of Count II of the 2013 Litigation Corrected Amended Complaint, Accordingly Count II Should be Dismissed

Novartis’ allegations in Count II of the Corrected Amended Complaint will remain duplicative and should be dismissed even if Novartis’ Motion to Amend the Asserted Claims in the 2012 Litigation is denied. Following Wockhardt’s motion to dismiss the original Complaint in the 2013 Litigation, Novartis sought leave to amend its Asserted Claims in the 2012 Litigation. (2012 Litigation, D.I. 51.) However, the denial of Novartis’ Motion to Amend the

Asserted Claims will have no effect on the duplicative nature of Count II of the 2013 Litigation Corrected Amended Complaint.

Novartis' Motion to Amend the Asserted Claims has not established good cause to amend the asserted claims. Novartis alleged only one basis for good cause, a change in business strategy. This Court has already emphatically rejected Novartis' sole assertion of good cause, explaining:

[I]t strains credibility in my opinion, quite frankly, to say that it that it was only at the time that this '189 patent came around that we realized we can do anything [on the '987 patent]. ***That just doesn't make sense to me.*** And I don't think it's supported by the record. I don't think the dates support that. I think that's very clear.

(2013 Litigation, D.I. 131, Mar. 1, 2013 TRO Hearing Tr. 76:23-77:3 (emphasis added).)

Accordingly, Novartis will be unable to amend its asserted claims.

Allowing Novartis to reassert the '987 patent in the 2013 Litigation if it is barred from asserting claims from the '987 patent in the 2012 Litigation completely undermines the purpose of the Local Patent Rules, which require "parties to crystalize their theories of the case early in litigation and to adhere to those theories once they have been disclosed." Confoy Ex. 2, Order Denying Plaintiffs' Motion for Leave to Amend Responses to Defendants' Invalidity Contentions, *Astrazeneca AB v. Dr. Reddy's Labs Inc.*, C.A. No. 11-2317-JAP-DEA, at 4 (D.N.J. Mar. 18, 2013) (*citing Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)). Moreover, the loop hole that would be created by allowing Novartis to avoid the requirements of the Local Patent Rules by reasserting the '987 patent against Wockhardt in a new suit would allow patent owners to avoid the effects of the Local Patent Rules, while defendants are given no such opportunity to avoid the consequences of their litigation choices.

Novartis already sued Wockhardt on the '987 patent and subsequently elected not to assert the claims of the '987 patent. If Novartis seeks to litigate the '987 patent, it must do so in the 2012 Litigation, by properly obtaining Court approval to amend the Asserted Claims. Novartis' attempts to skirt the Local Patent Rules and shift its litigation strategy have resulted in the improper, costly, unnecessary, and vexatious reassertion of the '987 patent in the 2013 Litigation. Such *gamesmanship* should not be condoned. Accordingly, even if Novartis' Motion to Amend its Asserted Claims is denied, Count II of the 2013 Corrected Amended Complaint should be dismissed.

IV. CONCLUSION

For the foregoing reasons, Count II of the 2013 Litigation Corrected Amended Complaint should be dismissed with prejudice as to Wockhardt, pursuant to Fed. R. Civ. P. 12(b)(6).

Respectfully submitted,

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